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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|---------------------|
| 10/798,064 | 03/11/2004 | Susanne Arney | 10-18-4 | 5680 |
| 7590 | 09/20/2007 | | EXAMINER | |
| Michael J. Urbano 1445 Princeton Drive Bethlehem, PA 18017-9166 | | | | PELLEGRINO, BRIAN E |
| ART UNIT | | PAPER NUMBER | | |
| | | 3738 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/798,064 | ARNEY ET AL. |
| | Examiner | Art Unit |
| | Brian E. Pellegrino | 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 June 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8,12,13,18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (WO 02/64019). Bailey et al. disclose the stent is made of metal material (page 16) that is known to be hydrophobic since metals do not absorb water. Bailey additionally discloses a region of the stent has a plurality of microstructures that can include electronic components, page 5, lines 3-11. Another stent is also disclosed that describes an array of microstructures or grooves and hydrophobicity can be controlled in dynamic fashion, page 10, lines 17-33. The cellular response and its effect on the microstructure clearly effects hydrophobicity. Bailey et al. also disclose chemically active substances adhered to the stent and that a voltage or energy can be applied to the device from an ex vivo source, page 23, lines 5-15. Bailey additionally discloses controlled release of substances by electrical energy, page 23, lines 23-31.

Claims 1,2,5-7,9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Momma et al. (2005/27350). Fig. 2 shows a stent body **42** that includes an array microstructures **38** and control device in the form of a membrane **46** to vary hydrophobicity. The array of microstructures include surfaces of exposed and having chemically active substances in two zones **52, 54** adhered thereto capable of release at different times. Momma et al. disclose the stent is a metal and thus has a hydrophobic

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surface, paragraph 35. Momma additionally discloses the chemically active substances can be different, paragraphs 21,45.

Claims 1,2,5-7,15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Shastri et al. (2004/115239). Shastri et al. disclose an implant having a plurality of fibers or particles of nanosize placed on its surface, paragraph 48,49. Shastri also discloses the nano-material can be silicon (paragraphs 41,52) a semiconductor material. Shastri additionally discloses the implant can be a stent, paragraph 54. The nanostructures have a size within the range of 4 μ m to 20nm, paragraph 69. Shastri discloses chemically active substances can be used on the device with control devices (polymer materials), paragraphs 75,79,82,84. These include cells that change the surface properties or hydrophobicity. Shastri discloses (paragraph 87) properties modified or controlled, including wettability that the Examiner interprets to be synonymous with hydrophobicity.

Claims 1,14 are rejected under 35 U.S.C. 102(b) as being anticipated by Oktay (2003/40791). Oktay shows (Fig. 10) a stent **1000** with an array of microstructures **1050,1060** on a region of the surface of the stent. Oktay discloses (paragraph 69) the stent structure is made of metal and thus is hydrophobic. Oktay further illustrates (11A-11C) the stent includes electrically controllable structures **1040** for latching the edges of the tubular body.

Claim Rejections - 35 USC § 103

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (WO 02/64019) in view of Momma et al. (2005/27350). Bailey et al. is explained supra. However, Bailey et al. fail to disclose different substances to be released into the implantation site. Momma et al. teach that different medicinal substances can be utilized to deliver to the implantation site for different purposes, paragraphs 21,45. It would have been obvious to one of ordinary skill in the art to incorporate different drugs on the stent as taught by Momma et al. in the stent of Bailey et al. such that it provides multiple therapeutic capabilities to encounter the biological responses of the body.

Response to Arguments

Applicant's arguments filed 6/27/07 have been fully considered but they are not persuasive. 1) Applicant begins by arguing a special definition of "hydrophobic" or how it should be interpreted. The Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851,1854 (Fed. Cir. 2001) and MPEP 2111.01. Applicant alleges the prior art materials do not have a hydrophobic surface despite the references of Bailey,Shastri, and Momma all disclosing materials for the stent surface that clearly have a low affinity for

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water or are in other words hydrophobic. Applicant states that absorption is irrelevant, however, that is not true since one of ordinary skill in the art would understand that stents and vascular prosthesis are to transport or provide a flow path for blood or other body fluids. They are not designed to absorb them.

2) Applicant argues the prior art does not disclose the hydrophobic surface is controlled by something dynamic. The first reference addressed by Applicant is Bailey and it is stated that the structures do nothing to effect surface hydrophobicity. However, the Examiner would like to note on page 10 of Bailey that an embodiment of a stent is disclosed that is affected "dynamically" or as a result of the cellular response to endothelialization to change the microstructure, thus effecting hydrophobicity.

3) Applicant argues that the reference (Momma) does not have controlled hydrophobicity. However, clearly one of ordinary skill in the art would understand that as biodegradable materials as a result of being less hydrophobic degrade until gone, change hydrophobicity. Once the degradable layer and drug is released and gone a more hydrophobic surface of the stent is exposed.

4) Applicant argues that Shastri fails to disclose the array of microstructures affect the hydrophobicity. However, the Examiner would like to refer Applicant to paragraph 82 which clearly explains that the microstructures dynamically control hydrophobicity with a functional moiety, such as the bioactive agents or cells etc. as mentioned in paragraph 84. Shastri then discloses the properties modified or controlled dynamically and as mentioned above including wettability, or in other words hydrophobicity.

5) Applicant argues that Roth does not disclose controlling hydrophobicity,

Applicant's arguments with respect to claim 14 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (8:30am-6pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

Brian E Pellegrino
BRIAN E. PELLEGRINO
PRIMARY EXAMINER